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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/408,905	09/29/1999	KENNETH WALSH	S1237/7011/E	4597

7590 02/26/2003

ELIZABETH R PLUMER
WOLF GREENFIELD & SACKS P C
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/408,905

Applicant(s)

WALSH, KENNETH

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 21 January 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 0.Claim(s) objected to: 5.Claim(s) rejected: 1-4.Claim(s) withdrawn from consideration: 6-38.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: Attachment

Response to Arguments

This action is in response to applicant's After-Final arguments filed 1-21-03 in Paper No. 30.

Applicant's argue that the rejection is based on a number of assumptions, any one of which if incorrect would over come the rejection. First, applicants argue that cells are not all alike and thus an apoptosis inhibitor reported to be effective in "neurons" would not, on its face, be expected to inhibit apoptosis in cardiac myocytes (Paper No. 30, page 1). Applicants respectfully submit (Paper No. 30, page 4) that the teachings of Datta do not teach that Akt is an inhibitor of apoptosis in "cardiac tissue".

This argument has been considered but is not found persuasive. Although the Datta *et al.* reference does not specifically include cardiac cells as a particular cell type where Akt would inhibit apoptosis, the reference teaches (page 231, 2nd column, 3rd paragraph) that Akt has been shown to suppress the apoptotic death of a number of cell types (including lymphoid, neuronal, fibroblast, and epithelial cells - see Paper No. 30, page 4 as so indicated by applicants) induced by a variety of stimuli. Thus, despite applicants arguments that differentiated cells from various tissues are widely recognized to be structurally and functionally dissimilar, such arguments cannot be found persuasive because one of ordinary skill in the art would have a *reasonable* expectation of success that Akt would inhibit apoptosis in cardiac myocytes since Akt inhibition of apoptosis was induced in many different cell types which are also recognized to be structurally and functionally dissimilar.

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Secondly, applicants allege that apoptosis inhibitors are not all alike, and that one apoptosis inhibitor cannot be substituted for another. This argument has been considered but is not found persuasive as applicants have not directed their arguments to the presently claimed subject matter, Akt- nor to the art of record. Applicant merely point out that certain growth factors are specific for certain receptors and that a growth factor would not communicate with a cell that did not express its cognate receptor.

Applicants further argue that apoptosis is not a single entity. Applicants argue that in the broadest sense, apoptosis has an intrinsic pathway and an extrinsic pathway wherein the intrinsic pathway functions through the mitochondria and is "largely sensitive to Akt". In contrast, applicants argue that the extrinsic pathway involves Fas ligand and caspase 8, and is largely insensitive to Akt. This argument has been considered but is not found persuasive because arguments that rely on a particular distinguishing features (i.e. different apoptotic pathways) are not persuasive when those features are not recited in the claims. Narrow limitation contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See *In re Philips Industries, Inc. v. State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims.

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Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
February 19, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000